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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,886	06/26/2000	Roy Sullivan	10546/56701	2146

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EXAMINER	
QADERI, RUNA S	
ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/603,886	SULLIVAN, ROY	
	Examiner	Art Unit	
	Runa S. Qaderi	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) 18-32 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to a system for performing a medical procedure, classified in class 600, subclass 429.

II. Claims 18-32, drawn to a method of performing a medical device, classified in class 600, subclass 429.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Invention I can be used to perform the method of tissue removal without relying on the step of defining tissue margins as claimed in Invention II.

During a telephone conversation with Patrick J. Fay on 11/7/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-32 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless – .
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4-8, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kreizman et al.

Kreizman et al. teaches an apparatus for performing a medical procedure, Fig 1. The system of Kreizman et al. teaches providing an X-ray tube (16) and an image receiver (18) for obtaining tomographic information about a region of interest thereby to perform a treatment procedure. The region of interest is a tumor and the treatment procedure is removal of the tumor tissue. The system further comprises a tissue removal device, a image display means, and a system controller. The tissue removal device is held by removal tool guiding stage. The position of the stage is constantly

registered to a point of reference, thereby also accounting for the position of the tissue removal tool, column 2 lines 23-34 and column 4 lines 11-18. A user interface enables for the placement of boundaries around the region of interest or tissue margins as claimed by the applicant, column 2 lines 19-23 and column 4 lines 6-10. The system controller includes control of the imaging system and the tissue removal tool, column 2 lines 34-47. The system of Kreizman et al. includes a means of marking the tumor tissue and providing a feedback system to control the therapy based on the removal of the marked tissue, column 4 lines 47-53.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 13, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreizman et al.

Kreizman et al. teaches a system of performing a medical procedure. The patent teaches means for positional registration of tissue removal device, means for system controller that includes control of radiation transmission and detection, means for obtaining tissue margin. Kreizman et al. does not teach tissue removal device including a distal radiopaque tip, a MRI imaging device, altering x-ray dose, and defining tissue

margins by utilizing an absolute measure of tissue or a percentage of a physical dimension of the lesion.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided a radiopaque distal tip to the tissue removal device of Kreizman et al. because it provides the equivalent means of detecting the position of the tissue removal device as taught by Kreizman et al. Further providing a radiopaque marker means to an invasive tool in an X-ray imaging system is a well known means of tracking the position of the device. It would have been obvious to one skilled in the art to modify Kreizman et al. such that the imaging modality used is magnetic resonance imaging. Such a modification merely involves the substitution of one well-known type of imaging modality for another. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the X-ray dose by the Kreizman et al. controller because the controller of the patent is capable of providing such function. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to incorporate the limitations of claims 16 and 17 because Applicant has not disclosed that defining tissue margins by utilizing an absolute measure of tissue or a percentage of a physical dimension of the lesion provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the tumor boundary or tissue margin means as taught by Kreizman because it provides for control of the tissue

removal procedure. Therefore, it would have been an obvious matter of design choice to modify Kreizman et al. to obtain the invention as specified in claims 16 and 17.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreizman et al. in view of Aida et al.

Kreizman et al. teaches a feedback control system for tissue removal. The patent does not teach further providing an alarm system in the controlling mechanism. Aida et al. teaches providing a control tissue therapy system that includes an alarming means to notify user of a deviation from the treatment plan. The alarming means can be either one or both of an alarm sound and a display message, column 12 lines 26-33. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further incorporate the alarming means of Aida et al. into the system of Kreizman et al. because it allows for controller of therapy procedure as taught by Aida et al. Further the alarming means is an additional function for controlling the therapy procedure as already taught by Kreizman et al.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kreizman et al. in view of Guo et al.

Kreizman et al. teaches a system of performing a medical procedure comprising a system controller. Kreizman et al. does not teach said controller to change the position of the imaging device. Guo et al. teaches a medical procedure comprising means of controlling the imaging device or the shooting means such that to change a

physical position of the device, column 2 lines 56-62 and column 15-16. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the limitation of controlling the imaging device such that to change a physical position of the device because it allows for adjusting the imager so provide a better image of the desired region as taught by Guo et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bucholz et al. (6,236,875) teaches surgical navigation systems including reference and localization frames.

Martin, Jr. (5,482,040) teaches tissue removal utilizing a system of defining tissue margins.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 746-7289 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RSQ
November 14, 2002

Marvin M. Lateef
Supervisory Patent Examiner
Group 3700